

§ 130A-131.17. Confidentiality of information; research.

(a) All information collected and analyzed by the Program pursuant to this Part shall be confidential insofar as the identity of the individual patient is concerned. This information shall not be considered public record open to inspection. Access to the information shall be limited to Program staff authorized by the Director of the State Center for Health and Environmental Statistics. The Director of the State Center for Health and Environmental Statistics may also authorize access to this information to persons engaged in demographic, epidemiological, or other similar scientific studies related to health. The Commission shall adopt rules that establish strict criteria for the use of monitoring Program information for scientific research. All persons given authorized access to Program information shall agree, in writing, to maintain confidentiality.

(b) All scientific research proposed to be conducted by persons other than authorized Program staff using the information from the Program, shall first be reviewed and approved by the Director of the State Center for Health and Environmental Statistics and an appropriate committee for the protection of human subjects which is approved by the United States Department of Health and Human Services pursuant to Part 46 of Title 45 of the Code of Federal Regulations. Satisfaction of the terms of the Commission's rules for data access shall entitle the researcher to obtain information from the Program and, if part of the research protocol, to contact case subjects.

(c) Whenever authorized Program staff propose a research protocol that includes contacting case subjects, the Director of the State Center for Health and Environmental Statistics shall submit a protocol describing the research to the State Health Director and to an appropriate committee for the protection of human subjects which is approved by the United States Department of Health and Human Services pursuant to Part 46 of Title 45 of the Code of Federal Regulations. If and when the protocol is approved by the committee and by the State Health Director pursuant to the rules of the Commission, then Program staff shall be entitled to complete the approved project and to contact case subjects.

(d) The Program shall maintain a record of all persons who are given access to the information in the system. The record shall include the following:

- (1) The name of the person authorizing access;
- (2) The name, title, and organizational affiliation of persons given access;
- (3) The dates of access; and
- (4) The specific purposes for which information is to be used.

The record required under this subsection shall be open to public inspection during normal operating hours.

(e) Nothing in this section prohibits the Program from publishing statistical compilations relating to birth defects that do not in any way identify individual patients. (1995, c. 268, s. 1.)